UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,394	10/31/2003	Henriette Draborg	10308.200-US	6155

25908 7590 06/16/2006

NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,394	DRABORG ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-22, 24, 25, 28, 32-40, and 43-54* is/are rejected.

7)☒ Claim(s) *23,27,29-31,41 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20060414*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's Amendments to the specification and claims in the Response filed 29 March 2006 cancel the original claims 1-15 and present the new claims 16-54. The new claims overcome the objections of record to the specification and to claims 1-15, and also overcome the rejections of record of claims herein over the disclosures of Brode et al., US 6,436,690, US 6,455,295, US 6,475,765 and US 6,599,730. The new claims 16-54 require, however, the statement of several new grounds of rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 48 is rejected, essentially for reasons of record, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection of claim 47 is a new ground of rejection necessitated by Applicant's amendment presenting the new claim 47. Claim 47 is indefinite because it depends from claim 17, which requires a substitution at position 62 but recites (1) a substitution set that does not include position 62 – see the first line at the top of page 14 of the Response filed 29 March 2006 – and (2) recites an ambiguous insertion, "*62aS" at line 8 of page 14 of the Response filed 29 March 2006. The two sets of substitutions render the claim ambiguous, thus indefinite. The first substitution set may be recited in a claim that depends from claim 16 and the second substitution set may be corrected in order to overcome this rejection.

This rejection of claim 48 corresponds to the rejection of record of the original claim 7 stated at page 11 of the communication mailed 29 September 2005. Applicant suggests at page 20 of the Response filed 29 March 2006 that the rewriting of claims

"address this rejection [of record]" but, like the original claim 7, new claim 48 is indefinite in reciting five modifications – S101G, S103A, G159D, M322V, and Q236H – that find no antecedent basis in the modifications of claim 16 from which claim 48 depends. Amending claim 48 to make it an independent claim describing a specific first modification together with the nine recited modifications will overcome this the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16 are 18 are rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,245,901. Applicant suggests at page 20 of the Response filed 29 March 2006 that the patented claim 1 does not "claim the protease variants of the present invention", but this is not persuasive. Although the conflicting claims are not identical, they are not patentably distinct from each other because modifications of the subtilase of the patented claim are included in modifications of subtilases of claims 16 and 18 herein which embrace the modifications recited for positions 62, 106, and 245 of the patented claim and the patented claim explicitly recites the Q12D modification of claims 16 and 18 herein.

Claims 16-22, 24-26, 28, 32-40, 43-46, and 50-52 are provisionally rejected, essentially for reasons of record, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78 and 122 of the copending, commonly-assigned, Application No. 09/957,806. Applicant suggests at page 20 of the Response filed 29 March 2006 that the claims of the co-pending application do not "claim the protease variants of the present invention", but this is not persuasive. Although the conflicting claims are not identical, they are not patentably distinct from each other where one of more of the subtilase substituents permitted at positions 4, 9,

12, 14, 15, 18, 19, 40, 45, 49, 51, 52, 55, 62, 89, 128, 131, 144, 145, 158, 167, 172, 186, 192, 203, 212, 245, 252, 254, 257, 262, 269, and 271 of claims 16-22, 24-26, 28, 32, 34-37, 39, 40, and 43-46 herein are explicitly recited in claims 78 and 122 of the copending application for the amino acid sequence of a "savinase-like" enzyme which is a subtilase. This is a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 16-18, 20, 50, 53, and 54 are rejected, essentially for reasons of record, under 35 U.S.C. § 102(b) as being anticipated by von der Osten et al., US 6,245,901, of record.

Applicant's arguments filed 29 March 2006 have been fully considered but they are not persuasive. Applicant suggests at page 20 of the Response that the new claims do not "disclose[d] of suggest[ed] by von der Osten et al. yet their disclosure, see claim 1, of the class I-S1 subtilase PD48 having "one or more" amino acid substitutions including S9K and R62K, meets the limitations of claims 16-18, 20, 50 herein which recite a lysine substitution at position 62 together with the substitution S9K. Von der Osten et al. also disclose, detergent compositions of claims 53 and 54 herein that comprise the modified subtilase of their claim 1 at col. 20 at lines 40-56.

Claims 16-18, 22, 32, 44, and 48-54 are rejected, essentially for reasons of record, under 35 U.S.C. § 102(e) as being anticipated by Poulouse et al., US 6,312,936, US 6,482,628, and US 6,927,055, of record.

Applicant's arguments filed 29 March 2006 have been fully considered but they are not persuasive. Applicant suggests at page 20 of the Response that the new claims do not "disclose[d] of suggest[ed] by any of Poulouse et al. yet their common disclosure in

Table II of their patents of generic subtilases comprising G20R and N62D substitutions, N62D and S128G substitutions, N62D and S256R substitutions, and a set of the several amino acid substitutions N62D, S101G, S103A, V104I, G159D, A232V, Q236H, Q245R, N248D, and N252K, meets the limitations of claims 16-18, 22, 32, 44, and 48-52. The further disclosures of Poulouse et al. of detergent compositions comprising the modified subtilases and other enzymes, e.g., other proteases, lipases, amylases, and cellulases, meets limitations of claims 53 and 54 herein.

Claims 16-18, 22, 32, 44, and 48-54 are rejected, essentially for reasons of record, under 35 U.S.C. § 102(e) as being anticipated by Ghosh et al., US 6,376,450, US 6,610,642, and US 6,838,425, of record.

Applicant's arguments filed 29 March 2006 have been fully considered but they are not persuasive. Applicant suggests at page 20 of the Response that the new claims do not "disclose[d] of suggest[ed] by any of Ghosh et al. yet their common disclosure in Table 3 of their patents of generic subtilases comprising G20R and N62D substitutions, N62D and S128G substitutions, N62D and S256R substitutions, and a set of the several amino acid substitutions N62D, S101G, S103A, V104I, G159D, A232V, Q236H, Q245R, N248D, and N252K, meets the limitations of claims 16-18, 22, 32, 44, and 48-52. The further disclosures of Ghosh et al. of detergent compositions comprising the modified subtilases and other enzymes, e.g., other proteases, lipases, amylases, and cellulases, meets limitations of claims 53 and 54 herein

Claims 16-18, 20, 50, 53, and 54 are rejected, essentially for reasons of record, under 35 U.S.C. § 102(e) as being anticipated by Roggen et al., US 2005/0181446, made of record herewith.

Applicant's arguments filed 29 March 2006 have been fully considered but they are not persuasive. Applicant suggests at page 20 of the Response that the new claims do not "disclose[d] of suggest[ed] by Roggen et al. yet their disclosure in claim 78 of a "savinase-like subtilase having "one or more" amino acid substitutions including S9K and R62K, meets limitations of claims 16-18, 20, 50 herein. Roggen et al. also disclose

detergent compositions comprising the modified subtilases, meeting limitations of claims 53 and 54.

Conclusion

Claims 23, 27, 29-31, 41 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
8 June 2006

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER